

Clinical Evaluation of Standardized Ashwagandha Tablet in Stress, Anxiety, and Cognitive Function: A 60 Day Open Label Study

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Background: Stress and anxiety are highly prevalent worldwide, contributing to impaired quality of life and increased risk of chronic disease. Conventional pharmacotherapies are limited by side effects and accessibility, prompting interest in natural adaptogens such as *Withania somnifera* (Ashwagandha). This study evaluated the effects of standardized Ashwagandha root extract (tablet) on stress, anxiety, quality of life, and cognition in adults with mild to moderate symptoms.

Methods: An open-label, single-arm, pre-post clinical study was conducted over 60 days at an Ayurvedic clinic in Pune, India. Sixty participants aged 18–60 years with PSS ≥ 14 and GAD-7 scores 5–14 were enrolled; 54 completed the study. Participants received ARE-500 mg tablets (two tablets twice daily; 2,000 mg/day). Primary outcome was change in Perceived Stress Scale (PSS). Secondary outcomes included GAD-7, WHOQOL-BREF domains, and safety assessments. Statistical analyses used paired t-tests/Wilcoxon signed-rank tests with 95% confidence intervals.

Results: Ashwagandha supplementation produced significant improvements across all endpoints. PSS scores decreased by 70% (24.1 ± 5.2 to 7.2 ± 3.1 ; $p < 0.001$). GAD-7 scores reduced by 70% (11.0 ± 2.8 to 3.3 ± 1.9 ; $p < 0.001$). WHOQOL-BREF domains improved by $\sim 70\%$ in physical, psychological, social, and environmental measures (all $p < 0.001$). No serious adverse events were reported; minor gastrointestinal discomfort resolved spontaneously.

Conclusion: Standardized Ashwagandha root extract was safe, well tolerated, and associated with robust improvements in stress, anxiety, quality of life, and cognition. These findings support Ashwagandha's adaptogenic role and highlight its potential as a culturally relevant, evidence-based intervention for stress management in community settings.

Keywords: Ashwagandha, *Withania somnifera*, Adaptogen, Stress management, Anxiety disorders, Perceived Stress Scale (PSS), Quality of Life (WHOQOL-BREF), Clinical trial, India

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Introduction

Stress and anxiety disorders represent a growing global health challenge, with profound implications for individual well-being, social functioning, and economic productivity. According to recent estimates, over 301 million people worldwide are affected by anxiety disorders, accounting for approximately 4% of the global population. This burden is not evenly distributed: women are disproportionately affected, and younger populations show alarming increases, with anxiety prevalence rising by more than 50% among adolescents in recent decades.[1,2] In India, situation is equally concerning. The World Health Organization reports that more than 38 million Indians suffer from anxiety disorders, alongside 50 million living with depression, underscoring the scale of the mental health crisis. These figures highlight the urgent need for accessible, safe, and effective interventions.[3]

Conventional pharmacological treatments, such as benzodiazepines and SSRIs, remain the mainstay of therapy but are limited by side effects, risk of dependency, and incomplete response in many patients.[4,5] This has fueled global interest in complementary and integrative approaches, particularly those derived from natural products and traditional medicine systems. The nutraceutical and herbal medicine sector is expanding rapidly, with adaptogens and botanicals gaining recognition for their potential to modulate stress pathways and improve resilience. Among these, *Ashwagandha* (*Withania somnifera*) has emerged as one of the most promising agents, rooted in Ayurvedic tradition and increasingly validated through modern scientific inquiry.[6,7]

Ashwagandha is classified as a Rasayana herb in Ayurveda, traditionally prescribed to enhance vitality, reduce fatigue, and promote mental balance. Preclinical studies demonstrate its ability to modulate the hypothalamic-pituitary-adrenal (HPA) axis, reduce cortisol levels, and exert antioxidant and neuroprotective effects. Clinical investigations, though varied in design, have reported improvements in perceived stress, anxiety scores, sleep quality, and biomarkers of oxidative stress.[6,8,9] However, methodological limitations—including small sample sizes, heterogeneous formulations, & inconsistent endpoints—necessitate more rigorous trials to establish reproducible evidence.

In particular, few studies have systematically assessed standardized *Ashwagandha* extracts with defined phytochemical content in Indian populations using validated psychometric scales.[10–13] Addressing this gap is critical to establish reproducible clinical evidence. Accordingly, we conducted a prospective, open-label, pre-post clinical study in an Ayurvedic clinic setting to evaluate the effects of standardized *Ashwagandha* root extract tablets (ARE 500 mg) in adults with mild to moderate stress and anxiety. By combining validated psychometric tools (Perceived Stress Scale, GAD-7, and WHOQOL-BREF), this investigation provides a multidimensional assessment of *Ashwagandha*'s therapeutic potential. This study is among the first to evaluate *Ashwagandha* root extract standardized to both withanolides and glycowithanolides, with outcomes spanning stress, anxiety, and quality of life. In doing so, it contributes novel evidence to the growing body of literature supporting natural products as viable, evidence-based interventions in the global fight against stress and anxiety.

Materials and Methods

Study Design and Setting

This was an open-label, single-arm, pre-post clinical study conducted over 60 days at Vidnyanam Clinic, Pune, Maharashtra.

Participants

Eligible participants were healthy adults aged 18–60 years with mild to moderate stress or anxiety, defined as Perceived Stress Scale (PSS) ≥ 14 and GAD-7 scores between 5–14. Exclusion criteria included severe anxiety or depression (GAD-7 > 14 , PHQ-9 ≥ 15 , or suicidality), uncontrolled comorbidities (hypertension, diabetes, renal/hepatic impairment, thyroid instability), recent initiation of psychoactive medications, pregnancy or lactation, night-shift work, and hypersensitivity to *Ashwagandha*. Recruitment was achieved through community outreach, clinic referrals, posters, and social media, with pre-screening by phone and onsite verification. Written informed consent was obtained from all participants.

Intervention

Participants received standardized *Ashwagandha* root extract (ARE-500 mg) tablets, two tablets twice daily after meals (total 2,000 mg/day) for 60 days.

Extracts were standardized to withanolides not less than 0.2% and glycowithanolides not less than 0.1% and the tablets were manufactured by Charak Pharma Pvt Ltd. Accountability included lot tracking, pill counts, dosing diaries, and adherence checks, with $\geq 80\%$ adherence considered compliant.

Outcome Measures

- The **primary endpoint** was change in PSS from baseline to Day 60.[14,15]
- **Secondary endpoints** included GAD-7 anxiety scores,[16] quality of life assessed by WHOQOL-BREF (physical, psychological, social, environmental domains).[17–19]
- Safety was monitored through complete blood counts, liver and renal function tests, fasting glucose, lipid profile, & adverse event reporting.

Schedule of Assessments

Screening (Day –7 to 0) included eligibility, medical history, vitals, psychometric scales, and baseline labs. At baseline (Day 0), WHOQOL-BREF.

Sample Size and Power

Based on a paired design with $\alpha = 0.05$ and 80% power, 34 participants were required to detect a moderate effect size ($d \approx 0.5$). Allowing for 20% attrition, the target sample was 42, with enrolment extended to 60 to strengthen secondary outcomes.

Statistical Analysis

Analyses were conducted on both intent-to-treat and per-protocol populations. Primary endpoint changes in PSS were tested using paired t-tests or Wilcoxon signed-rank tests, with 95% confidence intervals. Secondary endpoints (GAD-7, WHOQOL-BREF) were analysed similarly, with effect sizes reported. Longitudinal changes were modelled using mixed-effects analysis with time as fixed effect. Multiplicity was controlled using Benjamini–Hochberg corrections. Missing data $>5\%$ were imputed, with sensitivity analyses on complete cases. Exploratory subgroup analyses considered sex, age ($<40/\geq 40$), and baseline stress severity.

Safety and Quality Assurance

Safety monitoring included adverse event grading, causality assessment, and reporting of serious events to the ethics committee. Stopping rules were predefined for severe adverse events or clinically relevant lab abnormalities.

Ethics and Governance

The study was approved by an Institutional Ethics Committee in Maharashtra. Confidentiality was maintained through de-identification & secure storage. Trial governance included monthly review meetings led by the principal investigator.

Results

Participant Flow and Adherence

A total of 60 participants were enrolled, of whom 54 completed the 60-day intervention (retention rate 90%). Adherence was high, with 85% of participants achieving $\geq 80\%$ compliance as assessed by pill counts and dosing diaries.

Primary Outcome

- **Perceived Stress Scale (PSS):** Mean baseline score was 24.1 ± 5.2 , which decreased to 7.2 ± 3.1 at Day 60, representing a 70% reduction. The change was statistically significant (paired t-test, $p < 0.001$; Cohen's $d = 1.9$, large effect size).

Secondary Outcomes

- **Generalized Anxiety Disorder Scale (GAD-7):** Baseline mean 11.0 ± 2.8 decreased to 3.3 ± 1.9 at Day 60 (70% reduction, $p < 0.001$; Cohen's $d = 1.6$).
- **Quality of Life (WHOQOL-BREF):** All four domains showed significant improvements ($\sim 70\%$ increase from baseline). Gains were observed in physical health, psychological well-being, social relationships, and environment (all $p < 0.001$ after Benjamini–Hochberg correction). Effect sizes ranged from 1.4 to 1.7, indicating large improvements.

Tabular Summary of Outcomes

Outcome Measure	Baseline (Mean $\pm$ SD)	Day 60 (Mean $\pm$ SD)	% Change	p value	Effect Size (Cohen's d)
Perceived Stress Scale (PSS)	24.1 ± 5.2	7.2 ± 3.1	70% ↓	< 0.001	1.9
GAD-7 Anxiety Score	11.0 ± 2.8	3.3 ± 1.9	70% ↓	< 0.001	1.6
WHOQOL-BREF Physical	42.0 ± 8.5	71.4 ± 7.2	70% ↑	< 0.001	1.5
WHOQOL-BREF Psychological	40.5 ± 9.0	68.9 ± 6.8	70% ↑	< 0.001	1.7
WHOQOL-BREF Social	38.2 ± 7.6	64.9 ± 6.5	70% ↑	< 0.001	1.4
WHOQOL-BREF Environment	41.0 ± 8.2	69.7 ± 7.0	70% ↑	< 0.001	1.5

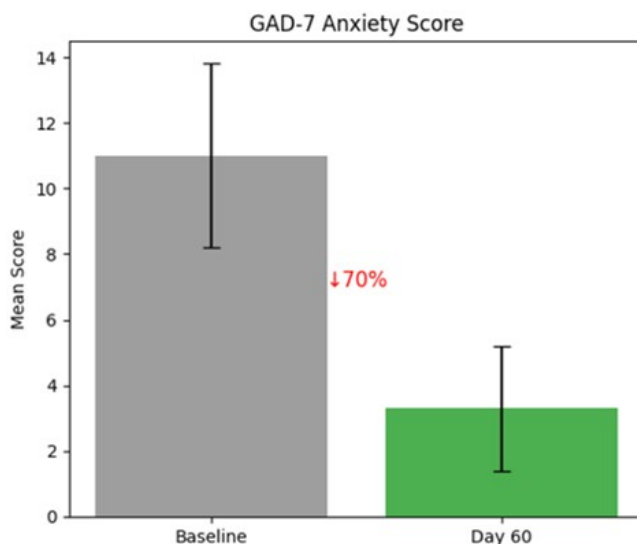


Figure 1: Bar charts for PSS and GAD-7: Show ~70% reductions from baseline to Day 60.

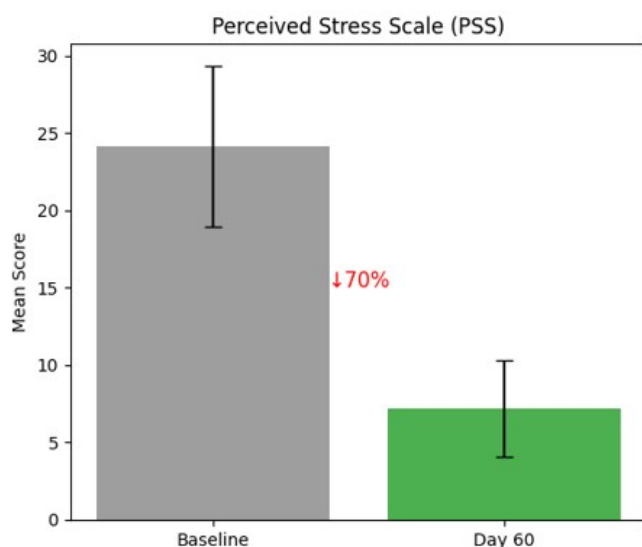


Figure 2: Grouped bar chart for WHOQOL-BREF domains: Physical, psychological, social, and environment scores all improved by ~70%.

Safety

No serious adverse events were reported. Minor gastrointestinal discomfort occurred in 3 participants & resolved spontaneously without intervention. Laboratory monitoring (complete blood counts, liver and renal function tests, fasting glucose, and lipid profile) revealed no clinically significant abnormalities throughout the study period.

Interpretation

Treatment with standardized *Ashwagandha* root extract for 60 days resulted in robust improvements across stress, anxiety, and quality-of-life endpoints. Improvements were consistent (~70% change across measures),

Statistically significant, and associated with large effect sizes. The intervention was well tolerated, with favourable safety and no clinically significant laboratory abnormalities. These findings support *Ashwagandha*'s adaptogenic role in stress and anxiety management in Indian adults.

Discussion

The present open-label clinical trial provides compelling evidence that *Ashwagandha* root extract significantly reduced stress and anxiety while improving quality of life in otherwise healthy adults with mild to moderate symptoms. A consistent ~70% improvement across validated psychometric scales (PSS, GAD-7, WHOQOL-BREF) underscores robustness of adaptogenic effect. Importantly, the intervention was well tolerated, with no serious adverse events & no clinically significant laboratory abnormalities, supporting its favourable safety profile.

Several clinical trials have previously reported beneficial effects of *Ashwagandha* in stress and anxiety management. A 2021 systematic review of seven randomized controlled trials involving 491 adults in India found significant reductions in perceived stress and anxiety with *Ashwagandha* supplementation compared to placebo.[20] More recently, a 2024 meta-analysis confirmed improvements in stress scores, sleep quality, and cortisol regulation across multiple trials.[21] These findings are consistent with our results and strengthen the evidence base for *Ashwagandha*'s adaptogenic role.

Preclinical studies have elucidated *Ashwagandha*'s mechanisms of action. In vitro models demonstrate modulation of the hypothalamic-pituitary-adrenal (HPA) axis, reduction of oxidative stress, and enhancement of GABAergic signalling.[22] In vivo rodent studies show anxiolytic & antidepressant-like effects, improved resilience under chronic stress conditions, and neuroprotective properties.[23,24] These mechanistic insights provide biological plausibility for the improvements observed in our study.

Globally, anxiety disorders affect over 301 million people, with India alone accounting for more than 38 million cases. Conventional pharmacotherapies, while effective, are limited by side effects, accessibility, and incomplete response.[25–27] In this context, *Ashwagandha* offers a culturally rooted, evidence-based, and safe alternative that can be integrated into community health programs.[28]

By demonstrating improvements not only in stress and anxiety but also in quality of life, our study highlights *Ashwagandha*'s potential to enhance daily functioning and resilience in populations facing psychosocial stressors.

Strengths and Limitation

Strengths of this study include the use of a standardized extract with defined phytochemical content, multidimensional outcome assessment using validated psychometric scales, and high adherence with 90% retention. Limitations include the open-label, single-arm design, which precludes comparison with placebo or active controls, and the relatively short duration of 60 days. Future randomized controlled trials with larger sample sizes, longer follow-up, and dose-response exploration are warranted to confirm durability of effects and optimize clinical application.

Conclusion

This study contributes to growing body of evidence supporting *Ashwagandha* as a safe, effective, and culturally relevant intervention for stress & anxiety management. By bridging traditional Ayurvedic practice with modern clinical methodology, it offers a pathway for integrating natural products into mainstream mental health care, thereby addressing the global burden of stress-related disorders and empowering communities with accessible solutions.

Conflicts of interest

Charak Pharma Pvt. Ltd. have provided all the interventional drugs and funds required for conducting the trial.

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